

August 25, 2005

Dr. E. J. Rauckman  
for Solutia, Inc.  
Toxicology and Regulatory Affairs  
120 Anise Court  
Freeburg, IL 62243

Dear Dr. Rauckman:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for tetrabutylhexamethylenediamine (TBHMD) posted on the ChemRTK HPV Challenge Program Web site on March 28, 2005. I commend Solutia, Inc. for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data in reporting test plans used to prioritize a chemical for further work.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The submitted data for the melting point, boiling point and partition coefficient endpoints are adequate for the purposes of the HPV Challenge Program.

*Vapor pressure.* The submitted estimated vapor pressure value is not adequate. Estimated values introduce uncertainties that become magnified in modeling applications. For the purposes of the HPV Challenge Program, estimated values are adequate when they are below  $1 \times 10^{-5}$  Pa. The submitter needs to provide a measured value for this endpoint according to OECD TG 104.

*Water Solubility.* EPA reserves judgment on the adequacy of the data provided pending clarification of the following issues: (1) The summary provides a measured value of 1.2 g/L. In the robust summary text, the value cited is 0.12 g/L. The submitter needs to revise to the correct measured value. (2) The summary cites an EPIWIN value of 0.05 g/L; EPA obtained a far lower EPIWIN value of 0.02353 mg/L (WSKOW v1.40). The submitter needs to check the units for its EPIWIN value. (3) No information was included on the method used. The submitter needs to provide as much information as possible about the experimental method. If the description is unavailable and the apparent large discrepancy between calculated and measured values is not resolved, the submitter needs to provide water solubility data according to OECD TG 105.

2. Environmental Fate. The submitted data for photodegradation, stability in water and fugacity are adequate for the purposes of the HPV Challenge Program.

*Biodegradation.* EPA agrees that biodegradation testing is needed. However, the submitter needs to provide ready biodegradation test data according to OECD TG 301 instead of an inherent test according to OECD TG 302.

3. Health Effects. The submitted data for the acute and repeated-dose toxicity endpoints are adequate for the purposes of the HPV Challenge Program. EPA agrees with the submitter's proposed testing for genetic toxicity (OECD TGs 471 and 473) and reproductive/developmental toxicity (OECD TG 421).

4. Ecological Effects. EPA agrees with the submitter's proposed testing for all ecotoxicity endpoints. Because amino groups are present, EPA suggests that a mitigation factor of toxicity for amines be determined, if necessary, using 20 mg/L humic acid in dilution water.

EPA will post this letter on the HPV Challenge Website within the next few days. We ask that Solutia advise the Agency, within 60 days of this posting on the Website, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: [oppt.ncic@epa.gov](mailto:oppt.ncic@epa.gov) and [chem.rtk@epa.gov](mailto:chem.rtk@epa.gov).

If you have any questions about this response, please contact Mark Townsend, Acting Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at [tsca-hotline@epa.gov](mailto:tsca-hotline@epa.gov).

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director  
Risk Assessment Division

Enclosure

cc: M. E. Weber  
J. Willis  
N. Patel